

Exhibit O

1 UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
2 CHARLESTON DIVISION
3

IN RE: ETHICON, INC. PELVIC REPAIR Master File No.
4 SYSTEM PRODUCTS LIABILITY LITIGATION 2:12-MD-02327
5 THIS DOCUMENT RELATES TO THE FOLLOWING
CASES IN THE WAVE 1 OF MDL 200:

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7
8 WENDY HAGANS,
9 Plaintiff,

10 v. Case No: 2:12-cv-00783
11 ETHICON, INC., ET AL.,
12 Defendant(s).

_____ /

13
14 DEPOSITION OF
BRIAN SCHWARTZ, M.D.

15
16 Taken in re: TVT-S litigation
17

18 DATE TAKEN: March 25, 2016
TIME: 2:00 p.m.
19 PLACE: 5237 Summerlin Commons Blvd.
Fort Myers, Florida

20
21
22 Examination of the witness taken before:

23 Elizabeth M. Brooks, RPR, FPR

2650 Airport Road South

24 Naples, FL 34112
25

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Brian Schwartz, M.D.

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Brian Schwartz, M.D.

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1 WHEREUPON,

2 BRIAN SCHWARTZ, M.D.,

3 having been duly sworn to tell the truth, testified upon
4 his oath as follows:

5 DIRECT EXAMINATION

6 BY MS. O'DELL:

7 Q Dr. Schwartz, I'm showing you what we
8 previously marked as Exhibit 1, and it is the notice of
9 deposition for your TVT-Secur deposition.

10 (Exhibit 1 marked for identification.)

11 BY MS. O'DELL:

12 Q You previously provided to us some invoices in
13 relation to your work with the Ethicon Wave cases.

14 Do you have any additional invoices for the
15 TVT-Secur?

16 A I do not.

17 Q What do you have in front of you?

18 A I have a binder marked TVT-Secur General
19 Report.

20 Q Okay. And I'm going to hand you a sticker,
21 and if you would mark that as Exhibit 5, please.

22 (Exhibit 5 marked for identification.)

23 BY MS. O'DELL:

24 Q Have you brought with you any other materials
25 related to your work on the TVT-Secur general report?

1 A No. I have some other articles as well, but
2 some of them are redundant, some aren't.

3 Q Reviewing now a stack of articles in a clip.
4 When did you obtain these articles?

5 A At various times.

6 Q Were they provided you to you by Ethicon
7 counsel?

8 A Some were, some were not.

9 Q And I'm going to mark them individually. If
10 you'll please identify in order what I've marked as
11 Exhibit 6.

12 (Exhibit 6 marked for identification.)

13 THE WITNESS: You want me to read the title
14 and first author?

15 BY MS. O'DELL:

16 Q I think first author, year and title would be
17 good.

18 A Okay. Neuman, 2011, Transobturator versus
19 Single Incision Suburethral Mini-slings for Treatment of
20 Female Stress Urinary Incontinence: Early Postoperative
21 Pain and Three-year Follow-up.

22 Q Did Ethicon counsel provide that to you?

23 A This was a mixed bag of articles that I
24 printed and that they provided.

25 Q Did you do a PubMed search -- excuse me -- for

1 your work in relation to the TVT-Secur?

2 A I did search for specific articles, yes.

3 Q What database did you use?

4 A Oh, I just used Google.

5 (Exhibit 7 marked for identification.)

6 THE WITNESS: It seems to get me almost every
7 article that I'm looking for.

8 BY MS. O'DELL:

9 Q I'm showing you what's marked as Exhibit 7.
10 It's Mostafa, 2014, Single Incision Mini-slings versus
11 Midurethral Slings.

12 Did you review that prior to writing your
13 report in this case?

14 A Let me look.

15 I don't remember.

16 Q Was that provided to you by Ethicon counsel?

17 A I believe it was.

18 (Exhibit 8 marked for identification.)

19 BY MS. O'DELL:

20 Q Let me show you what I'm marking as Exhibit 8,
21 which is a study by Walsh, TVT-Secur mini-sling for
22 Stress Incontinence, 2011.

23 Was that provided to you by Ethicon counsel?

24 A I don't know what this one was.

25 Q Did you review it?

1 A I did.

2 Q Did you have it prior to writing your report?

3 A I think I did.

4 Q Are you sure about that?

5 A No.

6 (Exhibit 10 marked for identification.)

7 BY MS. O'DELL:

8 Q I'm going to show you what I'm marking as
9 Exhibit 10.

10 A Is that Walsh 2011? So that's redundant, so I
11 did have that, the Walsh article.

12 Q Do you have the Schimpf article in your
13 notebook?

14 A 2014, yes.

15 (Exhibit 9 marked for identification.)

16 BY MS. O'DELL:

17 Q Okay. Let me show you what I've marked as
18 Exhibit 9. It's an article by Tincello dated 2011.
19 It's the TVT Worldwide.

20 A Yes. And that's in the booklet.

21 Q Do you have the Hota publication in your
22 booklet? It's year 2012, TVT-Secur Hammock Versus
23 TVT-obturator?

24 A It is not here, but I've read that. Is it in
25 my pile?

1 Q I'll hand it to you. I'm marking it as
2 Exhibit 11.

3 (Exhibit 11 marked for identification.)

4 MR. KOOPMANN: What was 10?

5 MS. O'DELL: I did it again? I'll remark it
6 as Exhibit 10.

7 BY MS. O'DELL:

8 Q Is Tang, 2014, in your notebook --

9 A Yes.

10 Q Do you have Bianchi-Ferraro, 2014?

11 A No.

12 Q I'm marking that as Exhibit 10.

13 Ethicon counsel provided that to you, true?

14 A I think so.

15 Q Is Tommaselli, 2015, in your notebook?

16 A Yes.

17 Q Abdel-farrah, 2011, is that in your notebook?

18 A No.

19 (Exhibit 12 marked for identification.)

20 MS. O'DELL: I'll mark it as Exhibit 12.

21 BY MS. O'DELL:

22 Q Do you have Cornu, C-O-R-N-U, 2010, Mid-Term
23 Prospective Evaluation of TVT-Secur Reveals High Failure
24 Rate? Is that in your notebook?

25 A No.

1 Q I'm marking it as Exhibit 13.

2 (Exhibit 13 marked for identification.)

3 BY MS. O'DELL:

4 Q Was this provided to you by Ethicon counsel?

5 A No.

6 Q And how did you obtain it?

7 A Online.

8 Q And when did you do that search?

9 A I don't know. Is there a date on the --

10 Q There is not a publication date on the
11 article.

12 Was it something that you located after you
13 wrote your report?

14 A No, no. I don't think so. I think I printed
15 them off, because there were some references in other
16 articles, that I would make a list and then go online
17 and search and print them off.

18 Q All right. And let me show you what I'm going
19 to mark as Exhibit 14.

20 (Exhibit 14 marked for identification.)

21 BY MS. O'DELL:

22 Q Dr. Schwartz, I'm marking as Exhibit 14 a
23 publication by North entitled A 2-Year Observational
24 Study to Determine Efficacy of Novel Single Incision
25 Procedure (Minitape), and it was published in the

1 British Journal of Obstetrics and Gynecology.

2 How did you obtain that article?

3 A Online.

4 Q And did you locate that article at the same
5 time you were searching and located the Cornu
6 publication, Exhibit 13?

7 A Most likely.

8 Q And were those articles that you located in
9 preparation for your deposition today?

10 A Yes.

11 (Exhibit 2 marked for identification.)

12 (Exhibit 3 marked for identification.)

13 BY MS. O'DELL:

14 Q I'm handing to you Exhibit 2. If you'll
15 please identify that for the record.

16 A That is the report for Gynecare TVT-Secur.

17 Q And please identify Exhibit 3.

18 A My recent CV.

19 (Exhibit 4 marked for identification.)

20 BY MS. O'DELL:

21 Q And then Exhibit 4?

22 A A reliance list of additional materials.

23 Q And, Doctor, the reliance materials we've
24 marked as Exhibit 4 is a document that was prepared by
25 counsel for Ethicon, true?

1 A Correct.

2 Q And is it fair to say that in rendering your
3 opinions in relation to the TVT-Secur, you've relied on
4 the materials in the notebook in front of you and the
5 other references that we have just marked?

6 A Those and any other -- any and all articles
7 that I've read, in the urology journals particularly.

8 Q Are you talking about in terms of your routine
9 reading or are you talking about specifically in
10 relation to TVT-Secur consulting work you are doing here
11 today?

12 A I would say it includes articles of my routine
13 reading.

14 Q What journals do you subscribe to?

15 A The Journal of Urology. Urology -- Renal &
16 Urology News. Oh, goodness. And several cancer
17 journals.

18 Q Do you subscribe to the International
19 Urogynecology Journal?

20 A I do not.

21 Q The American Journal of Obstetrics &
22 Gynecology?

23 A No.

24 Q Are you a member of AUGS?

25 A No.

1 Q Are you a member of IUGA?

2 A No.

3 Q Are you a member of what's referred to as
4 SUFU?

5 A No. That's a voluntary organization that I
6 have not joined.

7 Q Well, all professional organizations are
8 voluntary.

9 A There are no prerequisites for AUA members to
10 join SUFU. You just have to pay a fee and get the
11 journal.

12 Q Fair enough. But you are not a member?

13 A Correct.

14 Q And you don't get publications from them or
15 read their, you know, newsletters, updates, et cetera?

16 A Only when they are referred to in the journals
17 I mentioned.

18 Q Do you subscribe to any type of electronic
19 update that you receive, you know, just on your phone?
20 I've heard some of them referred to as UpToDate. There
21 are some other services?

22 A The American Urological Association sends a
23 daily e-mail with new information from all different
24 types of journals.

25 Q Do you find -- well, let me ask you this.

1 Would you agree with me that Nature Reviews
2 Urology is a reputable journal?

3 A I'm not familiar with Nature Reviews Urology.

4 Q Are you familiar with the group of journals
5 called Nature?

6 A Yes.

7 Q And do you find -- is Nature considered to be
8 a credible and a reliable group of journals?

9 A Nature is certainly a very credible journal.

10 Q Top-tier journal? Would you agree with that?

11 A I would agree.

12 Q In looking at your report and comparing it to
13 your report for the TVT-O, there are a number of
14 sections that are nearly identical. Certainly when you
15 look at roman numeral one of your report, which is
16 Exhibit 2, the background which covers your education
17 and training and your own clinical experience with
18 stress incontinence, I asked you a number of questions
19 about that portion of your report in the TVT-O
20 deposition.

21 Would you stipulate that your answers -- if I
22 were to re-ask the questions in relation to your
23 TVT-Secur report, are they the same or would be the
24 same?

25 A Yes.

1 Q So, in other words, I'm going to try my best
2 not to re-tread --

3 A Thank you.

4 Q -- where we have been before.

5 I'll ask you the same question in regard to
6 Section II of your report, roman numeral two, which
7 deals with urinary incontinence and covers the type,
8 definitions, risk factors --

9 A Okay.

10 Q -- diagnosis, impact on quality of life.

11 And I'm going to also include in this Section
12 III, the treatment options for stress urinary
13 incontinence.

14 Would you stipulate with me that your answers
15 to my questions, if I were to re-ask you now the same
16 ones I posed to you in the TVT-O deposition, they would
17 be the same?

18 A Yes.

19 MR. KOOPMANN: Counsel, just for my
20 clarification, are you talking about questions you
21 asked about those sections?

22 MS. O'DELL: Yes.

23 MR. KOOPMANN: I'll just lodge an objection,
24 because I don't recall you asking questions about
25 those particular sections.

1 MS. O'DELL: I think if you -- I went through
2 it in some detail, and specifically we had a nice
3 discussion about Page 6 of your report, but --

4 MR. KOOPMANN: Okay.

5 MS. O'DELL: But what I'm trying to do is to
6 make our time be used more constructively.

7 THE WITNESS: Thank you.

8 BY MS. O'DELL:

9 Q If you'll turn to Page 16, Dr. Schwartz, you
10 recount when Ethicon released the TVT-Secur sling for
11 commercialization, which was 2006.

12 When did you begin to use the TVT-Secur?

13 A Soon after it was made available.

14 Q And, if I'm remembering correctly, you've
15 placed approximately 300 TVT-Secur slings?

16 A Yes.

17 Q And that would be since 2006, I suppose?

18 A Since it was released, is when I started using
19 them, basically.

20 Q And then it was withdrawn from the market. Do
21 you recall what year?

22 A They were no longer produced as of two years
23 ago. I'm -- I don't know exactly.

24 Q Do you think that's a significant event, the
25 fact that Ethicon withdrew the TVT-Secur from the

1 market?

2 A I thought it was an event that was sad for me
3 and my patients.

4 Q In terms of your decisions to adopt a
5 procedure, what evidence are you looking for in terms of
6 efficacy and safety in order to make a decision to
7 implant a product?

8 A Well, I was very familiar with the Ethicon
9 mesh. I had been using it for many years and was very
10 happy with the results, and I saw an opportunity to use
11 a sling that required even less dissection, less
12 downtime following surgery, which in turn resulted in
13 higher patient satisfaction.

14 Q Now, when you began to use the TVT-Secur,
15 there was no clinical data to support the efficacy and
16 safety, true?

17 A The clinical data that I was aware of and
18 thought to be important was the pull-out strength,
19 because that indicated to me that I wasn't using a
20 device that was, was going to be clearly inferior to
21 what I was already using. And so, with that data, I
22 felt that the changes were otherwise so minimal that I
23 was comfortable progressing to a less invasive device.

24 Q Where did you get the pull-out data that you
25 are referring to?

1 A I was given that from discussions with our
2 local Gynecare representative.

3 Q That was not peer reviewed, that was not
4 published in a peer-reviewed journal, true, at the time
5 you received it?

6 A Yes. That is not how I was made aware of it.

7 Q And that was not data from studies involving
8 patients, it was bench testing, correct?

9 A Right. You cannot do that type of study on
10 patients.

11 Q Well, my point being, I asked you about
12 clinical data, and you responded by saying pull-out
13 data, which is not clinical data, as you point out, it
14 is bench testing.

15 So my question was, Did you begin to use
16 TVT-Secur at a time when there was no clinical data,
17 true?

18 A I did not have any -- yes. I did not have any
19 additional data, correct.

20 (Exhibit 15 marked for identification.)

21 Q Well, let me show you what's marked as Exhibit
22 15 to your deposition. This is an e-mail that was
23 exchanged among employees of Ethicon in relation to the
24 launch of the TVT-Secur.

25 You are familiar with Dr. Nilsson, correct?

1 A From the studies he's published.

2 Q He is an Ethicon consultant, correct?

3 MR. KOOPMANN: Object to form.

4 THE WITNESS: I just know him from the
5 studies, know his name.

6 BY MS. O'DELL:

7 Q And he is well regarded as a researcher in the
8 area of female incontinence, true?

9 A Once again, I just know him from the studies
10 that he's published.

11 Q One way or the other, you don't know?

12 A Right.

13 Q But obviously Ethicon was listening to
14 Dr. Nilsson, because, if you'll look down, midway down
15 the first page of Exhibit 15, you'll see, regarding the
16 proposed RCT, "Both Professor Nilsson and Professor
17 Artibani expressed their worries about us launching the
18 TVT-Secur with no clinical data."

19 Do you see that?

20 A I do.

21 Q So, when you adopted the TVT-Secur, there was
22 no evidence, clinical evidence to support its efficacy
23 in patients?

24 MR. KOOPMANN: Object to form.

25 BY MS. O'DELL:

1 Q True?

2 A Well, there was a tremendous amount of data
3 regarding the mesh that would be utilized in TVT-Secur.

4 Q You are talking about TVT and TVT-O studies?

5 A Correct.

6 Q But there were no studies that involved a
7 single incision, that involved pieces of fleece made of
8 vicryl PDS, you know, used to anchor the device in the
9 obturator internus muscle. That had not been studied in
10 women, true?

11 A Not that I know of.

12 Q You write on Page 18 of your report that,
13 "Overall, my TVT-Secur patients did great. If the
14 TVT-Secur was available, I would still be using it."

15 Did you maintain a log of the procedures that
16 you performed with the TVT-Secur?

17 A No.

18 MR. KOOPMANN: Object to form.

19 THE WITNESS: No.

20 BY MS. O'DELL:

21 Q Did you maintain a registry of outcomes for
22 the patients that you implanted with a TVT-Secur?

23 A No.

24 Q Did you have patients that you implanted with
25 the TVT-Secur have a failure of the device?

1 A Yes.

2 Q And how many?

3 A My experience mirrored that of the TVT
4 obturator in terms of effectiveness.

5 Q Are you comparing your effectiveness with the
6 TVT-O to the effectiveness of the TVT-Secur?

7 A For me.

8 Q So you are not referring to clinical
9 literature, you are referring to your experience?

10 A Right. That was my impression of what you
11 were asking.

12 Q Okay. I'm just making sure, because, when you
13 said "comparable to the TVT-O," I'm trying to understand
14 if you were talking about the literature or talking
15 about --

16 A Comparable to my experience with the TVT-O.

17 Q And what was that in terms of failure rate?

18 A The satisfaction rate was well between 80 and
19 90 percent, which was the same experience that I was
20 having with the TVT obturator.

21 Q 80 to 90 percent. Did I understand that
22 correctly?

23 A Yes. Yes.

24 Q In placing the TVT-Secur, did you prefer
25 the -- which method did you prefer, the U approach or

1 the hammock approach?

2 A The hammock approach.

3 Q If you will turn to Page 19. You begin a
4 section of your report where you go through two studies,
5 essentially.

6 How did you identify those studies for
7 inclusion in your report?

8 MR. KOOPMANN: Object to form.

9 THE WITNESS: Review of the literature that
10 was available.

11 BY MS. O'DELL:

12 Q You specifically note Shin and Neuman. You
13 specifically note those.

14 Did you consider others in your evaluation of
15 the efficacy and safety?

16 A Yes.

17 Q Okay.

18 A And there were -- yes. There were quite a few
19 that were available to choose from.

20 Q Okay. And what I'm trying to determine is how
21 you settled on Neuman and Shin in focusing, you know,
22 writing your report, Neuman, Shin and Tincello?

23 A I would have to review those studies and the
24 other studies. I mean, most of them will be because
25 they are quality studies.

1 Q So if you found them to be of inferior quality
2 as a study, you chose not to put those in, into the body
3 of your report?

4 A Depends what's available.

5 Q Well, what --

6 A The body of literature available.

7 Q What methodology or criteria do you use in
8 evaluating whether a study is credible or good quality
9 evidence?

10 A Well, the study design. There are certainly
11 Cochrane reviews. There are large meta-analyses. There
12 are data published by the various organizations, several
13 of which you've mentioned. Sometimes those are
14 available, sometimes they aren't available.

15 Q Let me show you what I've marked as Exhibit
16 16.

17 (Exhibit 16 marked for identification.)

18 BY MS. O'DELL:

19 Q This is a study by Hota, H-O-T-A, published in
20 the Journal of Female Pelvic Medicine & Reconstructive
21 Surgery in 2012. It compares the TVT-Secur to the
22 TVT-O. It's an original article. The authors are from
23 Harvard Medical School, or in associated hospitals in
24 the Boston area. It involves 43 women that were
25 randomized to TVT-S and 44 to TVT-O.

1 Do you find this to be a credible piece of
2 evidence to evaluate in determining the safety and
3 efficacy of the TVT-Secur?

4 A This is another piece of medical literature
5 that is worthwhile to have read and critiqued, and --

6 Q Did you consider it in reaching your
7 conclusions regarding the TVT-Secur?

8 A I did read this article, and I found the
9 results were so very different than most of the other
10 literature that I didn't include it.

11 Q And this is an article that came to your
12 attention after the writing of your report, true?

13 MR. KOOPMANN: Object to the form.

14 THE WITNESS: I don't know the answer to that.

15 BY MS. O'DELL:

16 Q This is not an article that you included in
17 your report, true?

18 A Correct.

19 Q And it's an article that, as I appreciate what
20 you just said, you discounted in terms of rendering your
21 opinions regarding the TVT-Secur, because you felt like
22 it was an outlier; is that a fair statement?

23 A Yes.

24 Q And wouldn't it also be true that this
25 publication is very negative regarding the efficacy and

1 the safety of the TVT-Secur?

2 MR. KOOPMANN: Object to the form.

3 THE WITNESS: It certainly reveals data
4 suggesting less efficacy.

5 BY MS. O'DELL:

6 Q Well, let's go through it. Not only efficacy
7 but also safety.

8 Looking at the results for efficacy for the
9 TVT-Secur, it says, "52.4 percent, or 22 of the 42,
10 participants randomized to the TVT-S had a positive
11 cough stress test, CST, result and evaluation after 12
12 weeks or one year."

13 In other words, they experienced a failure of
14 the device, true?

15 MR. KOOPMANN: Object to the form.

16 THE WITNESS: Insomuch as specifically
17 addressing the cough test. But, as you know from
18 the conclusion, the procedures resulted in similar
19 quality of life improvements.

20 BY MS. O'DELL:

21 Q Well, that's not really a fair recitation of
22 the study results, because, Doctor, if you would turn
23 over to Page 43 of the publication, on the right side it
24 says, "When assessed at one year after surgery the
25 incidence of a positive cough stress test result was

1 54.8 percent in the TVT-S group, compared to 9.1 percent
2 in the TVT-O group. The subjective cure rate, based on
3 the quality of life in symptom questionnaires, however,
4 indicates an overall improvement in the quality of life
5 and symptoms after both procedures. Because of the
6 significant difference noted in the primary outcome
7 cough stress test between groups at the time of this
8 interim analysis, the study was terminated early."

9 And so not a very good result for those in the
10 TVT-S group, true?

11 MR. KOOPMANN: Object to form.

12 THE WITNESS: True. Once again, my assessment
13 of this was it was an outlier, and when I review
14 articles, I have to, you know -- I try to take many
15 factors into account. And the -- having
16 discussions with colleagues regarding this
17 procedure, there were variable results, and some
18 had -- some had reported exceptional results and
19 some did not. And, to a degree, I attribute that
20 to the slightly more technically challenging nature
21 of performing the procedure.

22 BY MS. O'DELL:

23 Q In the Hota study, if you have it still in
24 front of you, on the same page, in regard to
25 complications, at Year 1 mesh exposure was noted in 19.1

1 percent of women who had the TVT-Secur and 0 percent of
2 the women who had the TVT, true?

3 A What table are you --

4 Q I was on the same page as we were before, Page
5 43.

6 A Yes.

7 Q On the left-hand side.

8 A Yes. Yes.

9 Q So --

10 A Yes. I see they had eight mesh exposures in
11 the Secur group and none in the obturator group.

12 Q So 19.1 of the percent of the women who had a
13 TVT-Secur suffered an exposure, correct?

14 A Correct. And, once again, that raises a big
15 flag for me in terms of the technique. You know, why
16 was this result so very different than my experience and
17 most other published reports?

18 Q Is it your -- is it your opinion that, if
19 there is a failure of a TVT-Secur, it's surgeon error?

20 MR. KOOPMANN: Object to the form.

21 THE WITNESS: A suboptimal result can always
22 be from surgeon error.

23 BY MS. O'DELL:

24 Q I'll ask the question from the other
25 direction.

1 Are there instances that you would admit that
2 are failures of the TVT-Secur?

3 A Are there instances where I have had failure
4 of the TVT-Secur? Yes.

5 Q That's not what I asked you.

6 A Okay.

7 Q I asked you if you take the position that the
8 TVT-Secur fails only in the setting of a surgeon not
9 implanting the device correctly.

10 A No. No. I don't take that position. There
11 are many reasons why incontinence procedures fail.
12 Every single method has failure.

13 Q And, despite the Hota publication, and others,
14 it's your position that the TVT-Secur is effective and
15 it is not inferior to other midurethral slings; is that
16 right?

17 A My position of my experience with my patients
18 is that the device did not have inferior efficacy.
19 Review of the data shows, or what I feel is the most
20 reliable data, shows efficacy that approaches the, and
21 sometimes equal to, the other sling techniques.

22 Q I think we marked it earlier. Let me check.
23 The Masata publication.

24 MR. KOOPMANN: Mostafa.

25 MS. O'DELL: Masata, M-A-S-A-T-A, randomized

1 clinical trial.

2 THE WITNESS: Mostafa.

3 MS. O'DELL: Maybe I didn't. I'll mark it as
4 Exhibit 17.

5 (Exhibit 17 marked for identification.)

6 BY MS. O'DELL:

7 Q Have you seen that, Dr. Schwartz?

8 A I don't recall seeing this.

9 Q And this is a publication from 2012 in the
10 International Journal of Urogynecology, and it's a
11 randomized trial. And you would agree with me that a
12 randomized controlled clinical trial is the gold
13 standard of clinical research, true?

14 A True. It certainly has to have enough
15 patients to be appropriately powered to have statistical
16 results.

17 Q And this is a randomized clinical trial
18 comparing the TVT-O to the TVT-Secur involving 197
19 women.

20 And if you'll look in the Results section,
21 you'll see that they randomized some patients in the
22 TVT-Secur to hammock and some to the U placement. And
23 68.8 percent of those in the TVT-Secur hammock group had
24 a negative stress test.

25 And, looking at it the other way, there was a

1 31.2 percent of the patients who had a positive stress
2 test. In other words, the sling was not being effective
3 for their stress incontinence, correct?

4 A Yes. I mean, the subjective reports are also
5 worth looking at, but I believe them to be fairly
6 similar here.

7 Q Well, it's very similar. For the TVT-Secur
8 hammock, the objective cure rates were 68.8, and 68.8 in
9 the subjective, so they are the same. So that means
10 it's 31 percent failure rate, true?

11 MR. KOOPMANN: Object to form.

12 THE WITNESS: Correct.

13 BY MS. O'DELL:

14 Q And, in regard to the TVT-Secur U group, there
15 was a 69.2 percent objective cure rate, a 61.5 percent
16 subjective cure rate. And so, from a subjective
17 standpoint, there was a 39.5 percent failure rate of the
18 TVT-Secur, correct?

19 A In the TVT-Secur U group?

20 Q Right.

21 A Is that what you are referring to?

22 Q That is what I'm referring to.

23 A Okay.

24 Q And if you'll turn over to Page 1409, Table 3.

25 In the TVT-S hammock group there was a 12.5

1 percent re-operation rate for SUI.

2 Do you see that?

3 A Yes.

4 Q And for the TVT-Secur U group there was a 10.8
5 percent re-operation for SUI.

6 Do you see that?

7 A Yes.

8 Q And you did not take this data into
9 consideration when rendering your opinions, true?

10 A This is not included in my report.

11 Q And are you familiar with the Barber study?
12 It was published in Obstetrics & Gynecology in 2012.

13 A I think I have that.

14 Q Do you have that, sir?

15 A Yes.

16 Q It's in your notebook?

17 A Yes.

18 Q Okay.

19 MS. O'DELL: I have a copy, if you need it.

20 MR. KOOPMANN: Sure. Thank you.

21 (Exhibit 18 marked for identification.)

22 BY MS. O'DELL:

23 Q And this is the publication by Barber,
24 Single-Incision Mini-Sling Compared With Tension-Free
25 Vaginal Tape for the Treatment of Stress Urinary

1 Incontinence, and it was published in 2012. So it's
2 also a randomized controlled clinical trial, true?

3 And that would be a Level 1 bit of evidence,
4 true?

5 A Likely.

6 Q Aren't RCTs always Level 1 evidence?

7 A There are some that aren't so good.

8 Q But in terms of the evaluation of clinical
9 literature, RCTs are Level 1 evidence? Can we agree on
10 that?

11 A Yes.

12 Q And this involved 263 patients.

13 And one year after surgery or implant, the
14 rate of cure for mini-sling was 55.8 percent.

15 Do you see that?

16 A I do.

17 Q The conclusion the authors draw is that, "The
18 mini-sling placed in a U position results in similar
19 subjective cure rates to TVT one year after surgery, but
20 postoperative incontinence severity is greater with the
21 mini-sling than with the TVT."

22 Did I read that correctly?

23 A You did. My concern with this study is the
24 low reported TVT success rate.

25 Q Do you think somehow these physicians didn't

1 know what they were doing?

2 A I can certainly not make that comment. I
3 don't, obviously, know them nor have worked with them,
4 and there is some, some very accomplished names I
5 recognize as part of the authors, but that is -- that's
6 just not a typical study reported success rate with TVT,
7 and the study is showing very similar results.

8 Q Well, in fact, you know what? Dr. Barber is
9 at Cleveland Clinic. You find Cleveland Clinic to be a
10 reputable institution, don't you, sir?

11 A I can't equate a good surgeon with a reputable
12 institution.

13 Q Okay. And do you know Mark Toblia?

14 A I don't.

15 Q Okay. He's an Ethicon consultant like
16 yourself. He's an expert in the Wave cases.

17 And do you have any reason to call into
18 question his surgical ability?

19 A I'm not questioning any of these authors'
20 surgical ability, and I did not bring up their surgical
21 ability. I was just commenting that, when you look at a
22 study, it's important to recognize whether the success
23 rates are typical for what is otherwise reported, and
24 this is not.

25 So I'm -- can infer from that that maybe this

1 is related to the results in the TVT-Secur group.

2 That's the most I can say about that.

3 Q The authors conclude on Page 136, "The minor
4 improvements in complication rates and the
5 post-operative patient experience demonstrated by the
6 TVT-Secur seem to be overshadowed by significantly
7 greater incontinence severity after surgery."

8 Did I read that correctly?

9 A I didn't see it, but --

10 Q It's the second to last sentence of the
11 publication.

12 A Okay. Right.

13 So I interpret that as their results were very
14 similar between Secur and retropubic TVT. But in those
15 who failed, those with the Secur failed worse.

16 Q Well, and those who failed in the Secur group
17 were -- 44.2 percent of those who were implanted with
18 the TVT-Secur experienced a failure of the device.

19 Correct?

20 A That's correct. That is what they report.

21 Q And this is a randomized controlled clinical
22 trial, Level 1 evidence, true?

23 A Correct.

24 Q And then let me ask you, did you include the
25 Barber study in your report?

1 A I don't believe so.

2 Q Now, you go on, on Page 21 of your report, and
3 you write, "A 2015 Cochrane review analyzed 81 separate
4 studies involving 12,113 women. Fifty-five of the
5 trials involving 8,652 women compared the use of the
6 transobturator route and the retropubic route. The
7 study did not include single incision sling like the
8 TVT-Secur. It does speak to the safety and efficacy of
9 the mesh used in the TVT-Secur."

10 Did I read that correctly?

11 A Yes.

12 Q And what basis do you have to conclude that
13 the Cochrane review, which does not involve the
14 TVT-Secur or mini-sling, is an appropriate study to
15 consider in rendering an opinion about the safety and
16 efficacy of the TVT-Secur?

17 A I'm simply inferring a comparison with the
18 mesh.

19 Q You are extrapolating?

20 A Yes.

21 Q That Cochrane review is the retropubic sling
22 versus the TVT-O sling. And you are saying you are
23 extrapolating that data onto the TVT-Secur, even though
24 that particular Cochrane review did not involve
25 mini-slings, correct?

1 A Correct.

2 Q We talked about, several times over the course
3 of the day, your confidence in Cochrane reviews as a
4 reliable piece of evidence for evaluating a midurethral
5 sling.

6 A Yes.

7 Q So wouldn't the better reference to understand
8 the safety and efficacy of mini-slings be a Cochrane
9 review that actually involved mini-slings?

10 A I would certainly want to consider that.

11 Q I mean, if you were going to cite a Cochrane
12 review, the one, you know, that you would want to cite,
13 in determining if the TVT-Secur is safe and effective,
14 would be a Cochrane review involving mini-slings, true?

15 MR. KOOPMANN: Object to form.

16 THE WITNESS: True. I believe here I was
17 merely referring to just safety of the mesh and
18 mesh exposure.

19 BY MS. O'DELL:

20 Q Well, you actually don't limit it to that.
21 You go on to talk about overall safety and overall
22 effectiveness.

23 And so is it fair to say that, if there is a
24 Cochrane review that covers mini-slings, you would defer
25 to the findings and data included in that review, true?

1 MR. KOOPMANN: Object to the form.

2 THE WITNESS: I would likely -- I would
3 certainly want to strongly consider using that
4 information.

5 BY MS. O'DELL:

6 Q Did you include in your report or in your
7 reliance materials the Cochrane review involving the
8 mini-slings?

9 A Do we have a title?

10 Q Is it in your report?

11 A I don't think it's in my report.

12 (Exhibit 19 marked for identification.)

13 BY MS. O'DELL:

14 Q Let me show you what I'm going to mark as
15 Exhibit 19 and ask if you've seen this before.

16 A Yes. I have read this.

17 Q You did not include this in your report, true?

18 A Correct.

19 Q And the title of Exhibit 19 is Single Incision
20 Sling Operations for Urinary Incontinence in Women,
21 reviewed by Nambiar. And this is a Cochrane review,
22 correct?

23 A Correct.

24 Q And if you'll turn to Page 2, you'll see that
25 under Background it says, "It should be noted that the

1 TVT-Secur is one type of single incision sling that's
2 been withdrawn from the market because of poor results."

3 Do you see that?

4 A Under Authors Conclusions?

5 Q Under Background, Page 2.

6 A It is my understanding that it was not
7 withdrawn from the market because of poor results.

8 Q Do you see the statement, sir?

9 A I do.

10 Q That is certainly a conclusion that the
11 Cochrane review reached, correct?

12 A That's what is written here.

13 Q Okay. If you'll turn over to Page 3, you'll
14 see under Main Results that they identify 31 trials
15 involving 3,290 women.

16 A Yes.

17 Q And the types of single incision slings
18 included in the review were -- and it lists them
19 starting with the TVT-Secur.

20 Do you see that?

21 A I do.

22 Q And it goes on to conclude, "Women were more
23 likely to be remain incontinent after surgery with
24 single incision slings. They were retropubic slings,
25 such as tension-free vaginal tape with a TVT."

1 Did I read that correctly?

2 A Yes.

3 Q And then the next paragraph, it says, "Single
4 incision slings resulted in higher incontinence rates
5 compared with the inside-out transobturator slings. The
6 adverse event profile was significantly worse,
7 specifically consisting of higher risk of vaginal mesh
8 exposure, bladder/urethral erosion, and operative blood
9 loss."

10 Do you see that?

11 A I do.

12 Q And then, if you move down further, it says,
13 "Overall results showed that TVT-Secur is considerably
14 inferior to retropubic and inside-out transobturator
15 slings."

16 Did I read that correctly?

17 A Yes.

18 Q And their conclusions are, "TVT-Secur is
19 inferior to standard mid-urethral slings for the
20 treatment of women with stress incontinence and has
21 already been withdrawn from clinical use."

22 Did I read that correctly?

23 A Yes.

24 Q Dr. Schwartz, wouldn't this Cochrane review
25 have been a much more appropriate Cochrane review to

1 include in your report than the 2015 review that you
2 included on Page 21?

3 MR. KOOPMANN: Object to the form.

4 THE WITNESS: It does state that evidence was
5 insufficient to suggest a significant difference
6 between any of the slings, and the comparisons
7 made.

8 BY MS. O'DELL:

9 Q It concludes TVT is inferior to standard
10 midurethral slings for the treatment of SUI.

11 And wouldn't that have been a more objective
12 and relevant Cochrane review to include in your report,
13 rather than the 2015 Cochrane review that related to
14 retropubic and TVT slings?

15 A I think this would be something reasonable to
16 consider.

17 Q And that is not something that you considered
18 and included in your report, true?

19 A True.

20 MR. KOOPMANN: Object to the form.

21 BY MS. O'DELL:

22 Q True?

23 A True.

24 Q If you look at Page 22, you cite a study by
25 the Society of Gynecologic Surgeons, Systemic Review

1 Group, and that would be the Schimpf study, correct?

2 A Do I have it here? Yes.

3 Q And if you will turn in the Schimpf
4 publication in your binder, to e15 -- and you find this
5 publication to be reliable, correct?

6 A Yes.

7 Q The Schimpf publication, if you will turn to
8 Page e.16, I think it is, found that "objective data
9 from traditional midurethral slings, TVT and
10 retropubic -- excuse me -- TVT and TVT-O slings were
11 superior to mini-slings."

12 True?

13 A I'm sorry. Where are you reading from on 16?

14 Q Yes. Excuse me. I should have pointed you
15 there. I forgot to, actually.

16 It says in the second full paragraph on the
17 left side, it says, "Meta-analysis of objective cure
18 outcomes significantly favored traditional, full-length
19 midurethral slings, all of which happened to be an
20 obturator sling, compared to mini-slings."

21 Do you see that?

22 A I do, and I see the next paragraph results as
23 well, which I think is important.

24 Q Okay. Just getting there.

25 "Results were similar for meta-analysis of

1 subjective cure outcomes. There were data included for
2 both obturator and retropubic traditional midurethral
3 slings. Traditional midurethral slings were found to be
4 superior to mini-slings."

5 TVT-Secur is included in the data for
6 mini-slings, correct?

7 A Yes. I believe so.

8 Q And, in fact, if you will turn over to the
9 page before, just turn back one page. At the bottom it
10 says, "There were 15 RCTs providing data for this
11 question, which represented three-arm and two-arm
12 studies by original design. The comparator arm of
13 traditional full-length midurethral slings was either an
14 obturator or retropubic; no studies compared Burch,
15 urethropexy or pubovaginal slings to mini-slings. The
16 majority of the studies in this category used a
17 TVT-Secur."

18 A Yes.

19 Q So, in fact, the data that they were looking
20 at for their evaluation of midurethral slings, in large
21 measure, was TVT-Secur, true?

22 A Correct.

23 Q And on that basis they concluded that
24 traditional full-length slings were to be recommended to
25 maximize cure rate?

1 A If one is only taking cure rates into account,
2 yes.

3 Q Well, if you take into -- if you are not going
4 to focus only on cure rates or efficacy, let's focus on
5 complications.

6 If you'll look at Page e16 again. It says,
7 middle paragraph, "Dyspareunia is rare with any type of
8 sling but is more common with a mini-sling than either a
9 retropubic or obturator sling. Mini-slings have the
10 highest rate of urethral perforation for either
11 retropubic or obturator, but the lowest rate of groin
12 pain compared to either route."

13 So, in other words, even from a safety
14 perspective the midurethral slings showed a higher rate
15 of dyspareunia and a higher rate of urethral perforation
16 in this particular study, true?

17 A True, with it being understood that the rates
18 of these are exceptionally low.

19 Q Now, when you quote the Schimpf article on
20 Page 22, Doctor, you say, "Overall the authors conclude
21 that, quote, The evidence supporting use of midurethral
22 sling and pubovaginal sling is high quality."

23 Do you see that? Page 22 of your report,
24 bottom of the page, last sentence.

25 A Yes.

1 Q That sentence does not relate to midurethral
2 slings, does it?

3 MR. KOOPMANN: Object to the form.

4 BY MS. O'DELL:

5 Q Excuse me. I'm sorry.

6 That sentence does not relate to mini-slings,
7 correct?

8 A Correct. Well, I don't know if it included --
9 I can't recall.

10 Q I'll represent to you that pubovaginal slings
11 were considered in a different category than
12 mini-slings, and midurethral slings were retropubic and
13 transobturator, they did not include mini-slings.

14 A Okay.

15 Q So that sentence is out of place in your
16 report. It does not relate to mini-slings, correct?

17 A I have to go back to -- yes.

18 Q That sentence does not relate to mini-slings,
19 correct?

20 A I tend to agree with you.

21 Q And in your discussion of the Schimpf
22 systematic review, you do not include in your report
23 their recommendation that patients be implanted with
24 traditional full-length midurethral slings instead of
25 mini-slings in order to maximize cure rates, true?

1 A True, with the qualifier that, taking into
2 account my experience with postoperative complications
3 and quick recovery balanced those results.

4 Q And so you outline some of the results from
5 the Schimpf review in your report, but you did not
6 include the conclusion regarding mini-slings because of
7 your personal experience in your practice? Is that a
8 fair statement?

9 A Well, there is -- there are -- I mean, to
10 follow the sentence we were just discussing, it did --
11 it does say that full length slings had better cure
12 rates.

13 Q Did you include the recommendation of Schimpf
14 and the other authors regarding mini-slings?

15 A No.

16 Q And they recommend not using mini-slings like
17 TVT-Secur, correct?

18 A They recommend a full-length midurethral
19 sling.

20 Q Now, we marked previously the Cornu study as
21 Exhibit 13, and is this an article that you identified
22 in preparation for your deposition today?

23 A Yes.

24 Q And it's not an article that you reference in
25 your report, true?

1 A True.

2 Q And this is a perspective study involving 45
3 patients, 41 who received a TVT-Secur under local
4 anesthesia and outpatient, and then I guess four that
5 had a TVT-Secur implanted, along with a Prolift, under
6 general anesthesia.

7 If you will look at the results of this study,
8 Dr. Schwartz, it appears, of this group, 42 percent of
9 the patients experienced a failure.

10 Do you see that?

11 A Yes.

12 Q And I'll direct you over to Page 3 of the
13 exhibit. And if you'll look -- and Page 3, on the
14 left-hand side, about midway down, it says, "12 patients
15 underwent supplementary surgery for SUI with TVT
16 replacement in 10 cases and a TVT-O in two cases."

17 Do you see that?

18 A I do.

19 Q And so, of the 41 patients who were involved
20 in this particular study, it appears that 29 percent had
21 to have a second operation within the first year, true?

22 A True.

23 Q The authors go on to say on Page 3, on the
24 right-hand side under Discussion, "In our experience,
25 this innovative device -- referring to the TVT-Secur --

1 failed to demonstrate high clinical efficacy on SUI
2 symptoms."

3 Did I read that correctly?

4 A I'm sorry. I am still looking for the
5 sentence. On 160?

6 Q Let's see. Mine is numbered a little bit
7 differently than yours, I think, because I don't -- I
8 didn't print it from the same source, but let's just go
9 to the conclusion. That may be easier.

10 So if you see the Conclusion, it says, "A
11 significant degradation over time was assessed with an
12 overall failure rate of 42 percent at three-year
13 follow-up."

14 Do you see that?

15 A Yes.

16 Q It says, "These results demonstrate the
17 importance of a long follow-up when a new device is
18 evaluated in the field of urinary incontinence.
19 Indications of TVT-Secur for SUI in women should be
20 reconsidered."

21 Did I read that correctly?

22 A Yes, you did.

23 Q And for these authors, they did not find or
24 the evidence did not -- let me strike that.

25 The results of that study concluded that the

1 TVT was -- TVT-Secur was not an effective product, true?

2 A That is true. This study was the most
3 significant outlier of all of the TVT-Secur studies I
4 could find. And this group -- this unique group did
5 have very poor results.

6 Q But their results are on par with Dr. Barber's
7 and others in the Foundation for Female Health and
8 Awareness Research Network that was published in ACOG.
9 And Dr. Cornu's results are on par with the Cochrane
10 review.

11 They are not really an outlier, are they, sir?

12 A Oh, no. This is an outlier.

13 Q All right. Okay. Moving on, Page 24 of your
14 report, which is Exhibit 2, you cite the AUGS and SUFU
15 position statement on mesh midurethral slings.

16 Are you familiar with that statement, sir?

17 A I am. I have to reread it.

18 Q Have you looked at the references cited in the
19 statement?

20 A In the body of the report?

21 Q No. I'm talking about the position statement
22 itself.

23 A Oh, yes. I would have to go back to this.

24 Okay.

25 Q If you'll turn to the last page of the

1 statement --

2 A Uh-huh.

3 Q -- in the reference list -- the reference
4 list.

5 And Dr. Schwartz, would you agree with me that
6 none of the references relied on in this statement
7 included data from midurethral -- excuse me, from
8 mini-slings?

9 A I did not see that any of this data referred
10 to mini-slings.

11 Q Okay. And in fact, the position statement is
12 referring to midurethral slings such as the retropubic
13 slings and the transobturator folding slings, true?

14 A I don't believe there was a specific comment
15 reflecting that in the statement.

16 Q So there was no -- there was no reference to
17 mini-slings in the position statement, true?

18 A Correct.

19 Q If you'll go continue forward in your report,
20 sir, you have a discussion -- one other quick question.

21 Are you a member of the International
22 Continence Society?

23 A No.

24 Q Were you aware of an ICS fact sheet before it
25 was provided to you in the context of litigation?

1 A I cannot recall.

2 Q And you're not a member of the American
3 College of Obstetrics & Gynecology, true?

4 A Correct.

5 Q And so you would not receive practice
6 bulletins from ACOG in your practice, true?

7 A No. But when there are statements made by
8 ACOG that affect urologic care as well, those would
9 usually be made clearly available to urologists, and
10 sometimes even printed in the urology journals.

11 Q Was ACOG Bulletin No. 145 provided to you in
12 any format outside of the context of this litigation?

13 A Are we -- can you tell me --

14 Q Page --

15 A -- what the title of that --

16 Q Page 26.

17 A Okay. 155?

18 Q Yes.

19 A Okay. I thought you said 145.

20 Q If I did, I'm sorry. I misspoke.

21 A I'm sorry. I can't recall.

22 Q Page 27 of your report at the top refers back
23 to actually the Practice Bulletin No. 155 for
24 obstetricians and gynecologists on urinary incontinence,
25 and you go on to write, "The guidelines state that,

1 quote, synthetic midurethral slings demonstrate efficacy
2 that is similar to the traditional suburethral fascial
3 slings, open colposuspension and laparoscopic
4 colposuspension, but are associated with fewer adverse
5 events."

6 That statement, Dr. Schwartz, is referring to
7 traditional full-length slings, not mini-slings,
8 correct?

9 A I believe so.

10 Q You go on to write, "The TVT-Secur sling is
11 only available in a laser-cut version."

12 And then you contrast mechanically cut TVT-O
13 slings to laser-cut TVT-Secur slings.

14 A My comment there was that I've -- that I use
15 both mechanically cut and laser-cut TVT-O slings.

16 Q But in regard to the dichotomy between
17 laser-cut and mechanical cut, that's not relevant to
18 TVT-Secur, true?

19 A That is not relevant.

20 Q And when you write, "The strong efficacy and
21 safety exhibited in the published literature on MUS, or
22 midurethral slings, predating the availability of
23 laser-cut mesh slings is consistent with a strong
24 efficacy and safety exhibited in the published
25 literature since laser-cut mesh has been available."

1 That sentence is not relevant to mini-slings,
2 correct?

3 MR. KOOPMANN: Object to the form.

4 THE WITNESS: Yes. That's not directly
5 related to mini-slings.

6 BY MS. O'DELL:

7 Q And in fairness, that's a holdover in your
8 TVT-O general report.

9 That sentence is a holdover from your TVT-O
10 general report, true?

11 A It certainly could be, if I had that.

12 Q I'll represent to you it's identical.

13 So if I represent to you that it's identical,
14 would you agree?

15 A I would. I would, yes.

16 Q Okay. I had a long discussion with you,
17 Dr. Schwartz, about contraction in our first deposition
18 today.

19 A Yes.

20 Q Would you stipulate that your testimony
21 regarding contraction in regard to the TVT-Secur would
22 be the same as what you testified to earlier with the
23 TVT-O?

24 MR. KOOPMANN: Object to the form.

25 THE WITNESS: Yes.

1 BY MS. O'DELL:

2 Q I want to ask you the same question in
3 relation to degradation.

4 Is your testimony regarding degradation of the
5 mesh used in the TVT-Secur the same as you testified
6 earlier in relation to the TVT-O?

7 MR. KOOPMANN: Object to the form.

8 THE WITNESS: Yes.

9 MS. O'DELL: Would you mind if we went off the
10 record just for a moment?

11 (A recess was taken at 3:45 p.m.)

12 (Back on the record at 3:50 p.m.)

13 MS. O'DELL: Back on.

14 BY MS. O'DELL:

15 Q Doctor, in your deposition relating to your
16 TVT-O report, I asked you a series of questions
17 regarding pore size and the weight of mesh, and
18 specifically about your experience in terms of -- strike
19 that and start again.

20 I asked you a series of questions related to
21 whether you had studied pore size and density of mesh,
22 whether you had published on those issues, and do you
23 recall those questions?

24 A I do.

25 Q Rather than me re-asking them, would you

1 stipulate that the answers that you gave in regard to
2 those questions regarding pore size, density and your
3 experience with those issues are equally applicable to
4 your TVT-Secur report?

5 MR. KOOPMANN: Object to the form.

6 THE WITNESS: I do.

7 BY MS. O'DELL:

8 Q On Page 30 of your report, at the bottom you
9 state that "Plaintiffs' experts have also suggested that
10 the removal of the TVT-Secur, if necessary, requires
11 expertise that many implanting surgeons do not possess.
12 First it should be noted that removal of the entire
13 TVT-Secur sling would be uncommonly indicated."

14 In Hota, for example, that we reviewed, there
15 was a 19 percent failure rate in the first year with a
16 re-operation in that same year of 19 percent.

17 Obviously, we have been through a series of
18 studies where there is a very high failure rate and a
19 greater than 10 percent re-operation rate.

20 Having said that, on what basis do you say
21 removal of the entire TVT-Secur sling would be
22 uncommonly indicated?

23 A Well, for all of the TVT slings that I've
24 implanted, I've never had to fully excise a TVT-Secur
25 sling or a TVT-O sling or a TVT sling.

1 Q You testified earlier that you had removed,
2 partially or in total, approximately 30 mesh devices.

3 How many of those were TVT-Secur devices?

4 A I'm going to -- I'm going to give you an
5 estimate of half.

6 Q Is removal of the TVT-Secur possible? I mean,
7 the whole sling, you know, the anchors and all, after
8 it's been implanted? Have you ever removed the entire
9 TVT-Secur, from end to end?

10 MR. KOOPMANN: Object to the form.

11 THE WITNESS: I have never had an occasion
12 where that was necessary.

13 BY MS. O'DELL:

14 Q So you have not attempted that procedure, in
15 other words, a complete removal of a TVT-Secur?

16 A Correct.

17 Q I'll show you what I'm marking as Exhibit 20.

18 (Exhibit 20 marked for identification.)

19 BY MS. O'DELL:

20 Q And is this the IFU for the TVT-Secur?

21 A I believe it is.

22 Q And if you'll turn to Page 20 of the actual
23 IFU, or I can refer to it by Bates number.

24 A Please, the latter.

25 Q 587. Begins the section entitled Warnings and

1 Precautions. Do you see that?

2 A Yes.

3 Q And then if you'll continue on to the next
4 page, and then also to Bates page ending 589, where it
5 discusses adverse reactions, are you familiar with this
6 portion of the IFU, Dr. Schwartz?

7 A Yes.

8 Q And you would agree with me that neither in
9 the Warnings and Precautions section nor in the Adverse
10 Reaction section is there any reference to pain?

11 A There is no -- as I read it, there is no
12 particular reference to pain, but all surgeons
13 understand that every surgical procedure is potentially
14 associated with pain, both acute and chronic.

15 Q And in this particular IFU, Ethicon has not
16 included a reference to pelvic pain, true?

17 A Same -- true. Same answer as before.

18 Q Dyspareunia is not included, true?

19 A True, but once again, all competent surgeons
20 understand that that is, just like pain, a potential
21 risk from pelvic, especially vaginal, surgery.

22 Q The Warnings and Precautions section and the
23 Adverse Reaction section does not include a reference to
24 an increased risk of overactive bladder, does it, sir?

25 A Once again, I take the same position, that

1 that's a potential complication with any type of
2 continence surgery.

3 Q And there is no reference to urgency or
4 frequency, true?

5 A Correct.

6 Q I ask you, in relation to the TVT, I'll ask
7 you again.

8 You've not consulted with a medical device
9 manufacturer regarding the drafting of an IFU, true?

10 A Correct.

11 Q And you have not drafted one on your own?

12 A Correct.

13 Q And other than skimming the guidelines that
14 were provided to you by Ethicon counsel, you are not
15 otherwise familiar with the FDA's guidelines for
16 warnings and precautions and adverse reactions contained
17 in an IFU, true?

18 MR. KOOPMANN: Object to the form.

19 THE WITNESS: Yes. Just what is stated in the
20 copy that we had gone into earlier.

21 BY MS. O'DELL:

22 Q You have on Page 33 of your report a section
23 on professional education, Dr. Schwartz.

24 Do you hold an opinion about Ethicon's
25 professional education program in relation to the

1 TVT-Secur?

2 A My experience has all been positive and very
3 helpful.

4 Q But you are not opining as to their overall
5 training program? Do I understand that correctly?

6 MR. KOOPMANN: Object to the form.

7 THE WITNESS: I'm just commenting upon what
8 their -- how their training program interacted with
9 me.

10 MS. O'DELL: I'll reserve. I have about seven
11 or eight minutes.

12 Thank you, sir.

13 CROSS EXAMINATION

14 BY MR. KOOPMANN:

15 Q Dr. Schwartz, does your TVT-Secur general
16 report that you have in front of you in Exhibit 5 set
17 forth your opinions regarding the TVT-Secur to a
18 reasonable degree of medical and scientific certainty?

19 A Yes.

20 Q My questions from this morning's deposition
21 regarding what you considered in evaluating the safety
22 and efficacy of the TVT obturator, and the adequacy of
23 the warnings and the TVT obturator IFU, would your
24 answer to those questions also apply to the TVT-Secur?

25 MS. O'DELL: Object to the form.

1 THE WITNESS: Yes.

2 BY MR. KOOPMANN:

3 Q And my questions from this morning's
4 deposition about your practice of evidence based
5 medicine and the hierarchy of levels of evidence, would
6 your answers to those questions this morning also apply
7 in this deposition regarding the TVT-Secur?

8 A Yes.

9 Q You mentioned that the TVT-Secur withdrawal
10 from the market was a sad event for you and your
11 patients.

12 What did you mean by that?

13 MS. O'DELL: Object to the form.

14 THE WITNESS: I found the addition of the
15 TVT-Secur another very useful tool in my
16 incontinence armamentarium to treat women with
17 stress urethral incontinence, and I feel that it
18 still has a very useful role in the treatment of
19 women with stress urinary incontinence. I feel
20 that, while there is some data that is poor, there
21 are other high quality studies that show very
22 favorable data, and my experience has mirrored the
23 more favorable ones.

24 BY MR. KOOPMANN:

25 Q Okay. Is the polypropylene mesh that is used

1 in the TVT-Secur the same exact mesh that's used in the
2 TVT and TVT-O slings?

3 MS. O'DELL: Object to the form.

4 THE WITNESS: The laser-cut mesh is exactly
5 the same.

6 BY MR. KOOPMANN:

7 Q The polypropylene material is the same
8 polypropylene in all of the slings?

9 A Correct.

10 Q The entire TVT family of slings?

11 A Correct.

12 Q Did you feel like the clinical data that
13 existed regarding the TVT and TVT-O slings supported
14 your use of the TVT-Secur sling when you started using
15 it?

16 MS. O'DELL: Object to the form. Asked and
17 answered.

18 THE WITNESS: Yes.

19 BY MR. KOOPMANN:

20 Q And the TVT-Secur sling lays at the midurethra
21 when implanted?

22 A All three slings should lay at exactly the
23 same position in the mid-urethra.

24 Q And by "all three slings," you mean the TVT
25 sling, the TVT-O sling and the TVT-Secur sling?

1 A Yes.

2 Q I just asked you some questions earlier today
3 about some registry studies by authors Abdel-fattah,
4 Jonsson Funk and Welk and Unger.

5 Do you remember that line of questioning?

6 A Yes.

7 Q Okay. While those studies may not parse out
8 what exact midurethral slings they are talking about,
9 are you of the opinion that those registry studies
10 support your opinions regarding the safety and efficacy
11 of the TVT-Secur?

12 MS. O'DELL: Object to the form.

13 THE WITNESS: They do.

14 MS. O'DELL: You said Jonsson, Abdel-fattah
15 and --

16 MR. KOOPMANN: Welk.

17 BY MR. KOOPMANN:

18 Q Counsel asked you some questions about the
19 Hota study earlier; is that right?

20 A Yes.

21 Q And that was Exhibit 16, correct?

22 A I have Hota as 11, Exhibit 11.

23 Q All right. And if you'll turn to the third
24 page of the Hota study, right above the Conclusions
25 section.

1 A Yes.

2 Q It says there, "Both TVT-S and TVT-O resulted
3 in improved quality of life in symptoms from baseline to
4 12 weeks. There was no difference between the groups
5 for either the PFDI-20 or the PFIQ-7."

6 Is that what they indicate there?

7 A Yes.

8 Q And then they indicate, "A similar pattern of
9 improvement was seen at one year." Is that correct?

10 MS. O'DELL: Object to the form.

11 THE WITNESS: Yes.

12 BY MR. KOOPMANN:

13 Q And in the right-hand column on that same
14 page, the paragraph starting with "when assessed," do
15 you see that paragraph?

16 A Yes.

17 Q They say in the second sentence of that
18 paragraph, "The subjective cure rates based on the
19 quality of life symptom questionnaires, however,
20 indicate an overall improvement in quality of life and
21 symptoms after both procedures," meaning both the
22 TVT-Secur and the TVT-O; is that right?

23 MS. O'DELL: Object to the form.

24 THE WITNESS: Yes.

25 BY MR. KOOPMANN:

1 Q If you'll go to the next page of the Hota
2 study, Page 44, the authors noted halfway down the
3 left-hand column that, "There was lower incidence of
4 postoperative pain at one week in the TVT-S group
5 compared to that in the TVT-O group."

6 Is that correct?

7 A Yes.

8 Q And they said that, "This could be attributed
9 to less dissection and trauma to the surrounding tissue
10 in the placement of TVT-S compared to TVT, which does
11 not penetrate the obturator membrane."

12 Is that what they said?

13 A Yes.

14 Q And then at the bottom of that column they
15 said, "Despite the fact that the TVT-S group had higher
16 post-operative TST, both groups had similar improvements
17 in quality of life."

18 Is that correct?

19 MS. O'DELL: Object to the form.

20 THE WITNESS: Yes.

21 BY MR. KOOPMANN:

22 Q You were asked about a study by Masata that
23 was marked as Exhibit 17.

24 Do you have that one?

25 A Not Mostafa?

1 Q Masata. Exhibit 17.

2 A Yes.

3 Q Turn to Page 1407 of that study, please.

4 A Yes.

5 Q Over in the right-hand column, in the second
6 full paragraph, about halfway down, it says, "In all
7 study groups surgery significantly improved quality of
8 life using the I-QOL and I-CIQ questionnaires and VAS."

9 Correct?

10 A Correct.

11 MS. O'DELL: Object to the form.

12 THE WITNESS: Correct.

13 BY MR. KOOPMANN:

14 Q And what did they note regarding overall
15 satisfaction in the groups studied in the next sentence,
16 Page 1407?

17 A Where it says there was no significant
18 difference?

19 Q Yes.

20 A There was no significance difference in the
21 overall satisfaction between the groups.

22 Q Meaning between the TVT-S group and the TVT-O
23 group?

24 MS. O'DELL: Objection. Misstates facts.

25 THE WITNESS: Yes.

1 BY MR. KOOPMANN:

2 Q In the Table 3 on Page 1409 -- do you see that
3 table?

4 A Yes.

5 Q And they list a P value for the various things
6 they studied or analyzed in Table 3; is that right?

7 A Yes.

8 Q And is the P value indicative of whether or
9 not the difference between the slings was significant,
10 statistically significant?

11 A Yes.

12 Q And for re-operation for SUI it indicates
13 "NA"; is that right?

14 A Correct.

15 Q And then for Tape Erosion it also notes "NA";
16 is that correct?

17 A Yes.

18 Q Which appears to mean there was not a
19 statistically significant difference between them?

20 A That's how I interpreted it.

21 Q You were also asked some questions about the
22 Barber study marked as Exhibit 18.

23 Do you have that one?

24 A Yes. Here. I have it.

25 Q Okay.

1 A Yes.

2 Q So the conclusion of the authors in this study
3 was, at least as stated in the abstract, "The mini-sling
4 placed in the U position resulted in similar subjective
5 cure rates to TVT one year after surgery but
6 postoperative incontinence severity is greater with the
7 mini-sling and the TVT."

8 Correct?

9 A Correct.

10 Q Yes.

11 A So as far as the similar subjective cure rates
12 between the mini-sling and the TVT were concerned, the
13 subjective cure rates were similar; is that right?

14 MS. O'DELL: Object to the form.

15 THE WITNESS: Yes.

16 BY MR. KOOPMANN:

17 Q And so the mini-slings's subjective cure rate
18 was similar to the gold standard, full-length
19 midurethral sling?

20 MS. O'DELL: Object to the form.

21 THE WITNESS: That's what it states.

22 BY MR. KOOPMANN:

23 Q And turn to Page 333, please.

24 A Okay.

25 Q In the right-hand column in the last

1 paragraph, the authors noted that, "Patients receiving
2 TVT were more likely to have a bladder perforation
3 during sling placement than those in the mini-sling
4 group."

5 Is that correct?

6 A Correct.

7 Q And if you'll turn to the next page, Table 4,
8 they note some more detailed data regarding subjective
9 cure; is that fair to say?

10 A Yes.

11 Q Okay. And at the bottom of Table 4 there is a
12 section that's labeled Patient Global Assessment of
13 Improvement.

14 Do you see that?

15 A Yes.

16 Q That shows that, for the mini-sling group, 63
17 of 109 patients were very much better?

18 A Yes.

19 Q And 24 of 109 patients were much better?

20 A Yes.

21 Q And then 11 out of 109 patients were somewhat
22 better?

23 A Yes.

24 Q So that's 98 patients out of 109 said they
25 were either very much better, much better or somewhat

1 better with the mini-sling?

2 A Yes. Ninety of the patients.

3 Q They noted in the left-hand column below Table
4 4, towards the bottom of that column, that, "No mesh
5 exposures were noted during the follow-up in the
6 mini-sling group and one individual in the TVT group had
7 mesh exposure noted at six weeks that was successfully
8 managed with topical estrogen and observation."

9 Is that right?

10 A Correct.

11 Q If you will turn to Table 5, please, Page 336.

12 They noted in Table 5, up at the top in the
13 Intraoperative Complications section that, for bladder
14 injuries, there was only one bladder injury with
15 mini-slings, correct?

16 A Yes.

17 Q And then how many bladder injuries were there
18 with the tension-free vaginal tape, full-length sling?

19 A Six.

20 Q And then, for the re-operation rates, which
21 are listed at the bottom of that table, there were two
22 re-operations for incontinence surgery in the mini-sling
23 group, correct?

24 A Correct.

25 Q And then there were four in the tension-free

1 vaginal tape full-length sling group, correct?

2 A Correct.

3 Q Do you have the Nambiar study, the Cochrane
4 review that was marked as Exhibit --

5 A Nineteen?

6 Q -- nineteen.

7 In the Main Results section of Exhibit 19, in
8 the paragraph starting off with "single incision slings
9 resulted" -- do you see that paragraph?

10 A Yes.

11 Q Okay. About halfway through that paragraph
12 the authors noted that, "Postoperative pain was less
13 common with single incision slings and rates of
14 long-term pain or discomfort were marginally lower but
15 the clinical significance of these differences is
16 questionable."

17 Did I read that correctly?

18 A Yes.

19 Q In your experience, in your patient
20 population, using the TVT-Secur slings, did patients
21 have lower rates of immediate postoperative pain than
22 they did following full-length sling procedures?

23 A Yes.

24 Q The next paragraph, starting with "evidence
25 was insufficient."

1 A Yes.

2 Q A few lines down in that paragraph the authors
3 noted that, "Risks of postoperative and long-term
4 groin/thigh pain were slightly lower with single
5 incision slings, but overall evidence was insufficient
6 to suggest a significant difference in the adverse event
7 profile for single incision slings compared with
8 transobturator slings."

9 Is that right?

10 A That's how it reads.

11 Q And is a Cochrane review essentially a
12 systematic review and meta-analysis of a larger body of
13 literature?

14 A Yes.

15 Q And did you consider, in forming your
16 opinions, other systematic reviews and meta-analyses of
17 bodies of literature pertaining to the TVT-Secur?

18 MS. O'DELL: Object to the form.

19 THE WITNESS: Yes.

20 BY MR. KOOPMANN:

21 Q Counsel asked you earlier about the authors'
22 conclusions in that Nambiar study about the TVT-Secur
23 being inferior to standard midurethral slings for the
24 treatment of women with stress incontinence.

25 Is it fair to say that you've read lots of

1 data reporting widely varying efficacy rates for the
2 TVT-Secur sling?

3 MS. O'DELL: Object to the form.

4 THE WITNESS: That is correct.

5 BY MR. KOOPMANN:

6 Q Some studies you've reviewed, including RCTs,
7 report very strong efficacy rates for the sling?

8 MS. O'DELL: Object to form.

9 THE WITNESS: Yes.

10 BY MR. KOOPMANN:

11 Q And other studies, including RCTs, report
12 lower efficacy rates?

13 A Correct.

14 Q And the high efficacy rates that you see
15 reported in the literature is consistent with your
16 experience using the TVT-Secur sling?

17 A Yes.

18 Q The authors also concluded in this article by
19 Nambiar and colleagues, "Not enough evidence has been
20 found on other single incision slings compared with
21 retropubic or transobturator slings to allow reliable
22 comparisons."

23 Is that right?

24 MS. O'DELL: Object to the form.

25 THE WITNESS: Yes.

1 BY MR. KOOPMANN:

2 Q You were asked some questions about the
3 Schimpf study --

4 A Yes.

5 Q -- earlier.

6 Do you have that in front of you?

7 A Yes.

8 Q Turn to Table 3, please, in that study.

9 A Yes.

10 Q Table 3 again reports the rates of adverse
11 events, or various types of adverse events and various
12 types of incontinence treatments, correct?

13 A Yes.

14 Q And what was the rate of hematoma for
15 mini-slings?

16 A 0.85 percent.

17 Q And what was the rate of hematoma for Burch
18 procedures?

19 A 1.4 percent.

20 Q And what was the rate of hematoma for
21 pubovaginal sling procedures?

22 A 2.2 percent.

23 Q And what was the rate of dyspareunia for
24 mini-slings?

25 A 0.74 percent.

1 Q And what was the rate for pubovaginal slings?

2 A 0.99 percent.

3 Q And what was the rate of return to the
4 operating room for erosions in the mini-sling group?

5 A 1.4 percent.

6 Q And what was the rate of return to operating
7 room for erosions in the pubovaginal sling group?

8 A 1.6 percent.

9 Q And what were the rates in the retropubic and
10 obturator groups, respectively?

11 A 1.9 percent and 2.7 percent.

12 Q And retropubic and transobturator slings are
13 considered to be the gold standard of incontinence
14 treatment?

15 MS. O'DELL: Object to the form.

16 THE WITNESS: Yes.

17 BY MR. KOOPMANN:

18 Q What was the rate of exposure in the
19 mini-sling group?

20 A 2.0 percent.

21 Q And what was it in the pubovaginal sling
22 group?

23 A 5.4 percent.

24 Q What was the rate of wound infection in the
25 mini-sling group?

1 A 0.31 percent.

2 Q And what was the rate in the pubovaginal sling
3 group?

4 A 2.6 percent.

5 Q What was the rate of wound infection in the
6 Burch procedure group?

7 A 7.0 percent.

8 Q What was the rate of urinary tract infection
9 in the mini-sling group?

10 A 3.6 percent.

11 Q What was the rate in the pubovaginal sling
12 group?

13 A 4.2 percent.

14 Q And what was the rate in the Burch procedure
15 group?

16 A 5.9 percent.

17 Q What was the rate of bowel injury in the
18 mini-sling group?

19 A 0.74 percent.

20 Q What was the rate of bowel injury in the Burch
21 procedure group?

22 A 3.13 percent.

23 Q What was the rate of nerve injury in the
24 mini-sling group?

25 A Zero.

1 Q What was the rate of OAB or urgency in the
2 mini-sling group?

3 A 5.4 percent.

4 Q And what was the rate of overactive bladder or
5 urgency in the Burch procedure group?

6 A 4.3 percent.

7 Q What was the rate in the pubovaginal sling
8 group?

9 A 8.6 percent.

10 Q What was the rate of urinary retention lasting
11 more than six of weeks postoperatively in the mini-sling
12 group?

13 A 3.3 percent.

14 Q What was the rate of retention lasting more
15 than six weeks postoperatively in the pubovaginal sling
16 and Burch procedure groups, respectively?

17 A 7.5 percent and 7.6 percent.

18 Q What was the rate of groin pain in the
19 mini-sling group?

20 A 0.62 percent.

21 Q What was it in the Burch procedure group?

22 A 1.1 percent.

23 Q What was the rate of leg pain in the
24 mini-sling group?

25 A 1.6 percent.

1 Q What was the rate of bladder perforation in
2 the mini-sling group?

3 A 0.85 percent.

4 Q And what was the rate of bladder perforation
5 in the pubovaginal sling group?

6 A 2.3 percent.

7 Q What was the rate of bladder perforation in
8 the Burch procedure group?

9 A 2.8 percent.

10 Q Is the Schimpf study one of the studies that
11 you've reviewed and relied on in forming your opinion
12 regarding the TVT-Secur's safety?

13 A Yes.

14 Q When you look at systematic reviews and
15 meta-analyses of literature that various authors have
16 published, do those authors sometimes set out to find
17 the literature regarding a certain device, and both the
18 systematic review and meta-analyses will end up
19 analyzing different sets of literature?

20 MS. O'DELL: Object to the form.

21 THE WITNESS: Typically the systematic reviews
22 will look at -- will not look at the same group,
23 the same group of studies or all of the same
24 studies.

25 BY MR. KOOPMANN:

1 Q Even though they may set out to look at all of
2 the literature about a certain device, they end up
3 looking at different sets, correct?

4 MS. O'DELL: Object to the form.

5 THE WITNESS: Typically, yes.

6 BY MR. KOOPMANN:

7 Q You were asked some questions earlier about
8 and Cornu study that was marked as Exhibit 13.

9 Do you recall that?

10 A Yes.

11 Q And that study is not a randomized controlled
12 trial; is that right?

13 A Correct.

14 Q They only looked at TVT-Secur patients?

15 A Yes, with or without Prolift.

16 Q And then on Page 4, right before the
17 Conclusions section, the authors of that Cornu study
18 noted, "This evaluation limited by a small number of
19 patients treated and patient selection criteria which
20 were very large to reflect daily practice. Moreover,
21 the design of this study is prospective but did not
22 include a comparison group."

23 Is that right?

24 A Correct.

25 Q So we don't know what the surgeons would have

1 seen in a comparison of the TVT-Secur with the TVT or
2 TVT-O; is that fair?

3 MS. O'DELL: Objection to form.

4 THE WITNESS: That is fair.

5 BY MR. KOOPMANN:

6 Q You were asked some questions about a
7 statement in your report at Page 27 that said, "The
8 strong efficacy and safety exhibited in the published
9 literature on midurethral slings predating the
10 availability of laser-cut mesh slings is consistent with
11 a strong efficacy and safety exhibited in the published
12 literature since laser-cut mesh has been available."

13 Is that correct?

14 A Correct.

15 Q Does the data regarding -- strike that.

16 Is that statement that you made true with
17 respect to the data on laser-cut mesh slings in general
18 versus mechanically cut mesh slings in general?

19 MS. O'DELL: Object to the form.

20 THE WITNESS: Yes.

21 BY MR. KOOPMANN:

22 Q You were asked some questions about the TVT
23 IFU that was marked as Exhibit 20, and you were asked
24 whether pain or pelvic pain or dyspareunia were noted.

25 Do you recall those questions?

1 A I do.

2 Q One of the things noted in the Warnings and
3 Precautions section of the IFU for the TVT-Secur marked
4 as Exhibit 20 is -- well, it says, "The Gynecare
5 TVT-Secur system should be used with care to minimize
6 the chance of damage to large vessels, nerves, bladder
7 and bowel."

8 Do you recall reading that in the IFU?

9 A Yes.

10 Q And then it says, in the Adverse Reactions
11 section, "Punctures or lacerations or injury to vessels,
12 nerves, bladder, urethra or bowel may occur during
13 instrument passage and may require surgical repair."

14 Do you recall reading that in the IFU?

15 A Yes.

16 Q And do those two items in the IFU tell you, as
17 somebody that went to medical school and did a residency
18 and has been a practicing urologist for many years, that
19 pain, pelvic pain or dyspareunia could result from the
20 use of the device?

21 MS. O'DELL: Objection to form.

22 THE WITNESS: Yes.

23 BY MR. KOOPMANN:

24 Q With a punctured or lacerated nerve, for
25 instance, pain, pelvic pain or dyspareunia could result?

1 A Yes.

2 Q You were asked some questions about the AUGS
3 and SUFU position statement earlier.

4 Do you recall those questions?

5 A Yes.

6 Q Okay. And do the statements made in that
7 position statement relating to polypropylene -- strike
8 that.

9 Do the statements made in that position
10 statement relate to polypropylene midurethral slings
11 made of the exact same mesh as the TVT-Secur?

12 A Yes.

13 Q One of the studies you relied on in forming
14 your opinions in this case is a systematic review and
15 meta-analysis by Dr. Colin Walsh; is that right?

16 MS. O'DELL: Object to the form.

17 THE WITNESS: Yes.

18 BY MR. KOOPMANN:

19 Q And that systematic review and meta-analysis
20 looked at 1,178 women undergoing the TVT-S procedure
21 from ten studies, correct?

22 MS. O'DELL: Barry, do you have a copy of
23 that?

24 THE WITNESS: Yes.

25 BY MR. KOOPMANN:

1 Q And in that study they found both objective
2 and subjective cure rates at 12 months with 76 percent?

3 A Yes.

4 Q They found a 2.4 percent incidence of mesh
5 exposure in the first year?

6 A Yes.

7 Q They found a dyspareunia rate of what?

8 A 1 percent.

9 Q And what was the rate of return to theater for
10 complications in the TVT figure?

11 A 0.8 percent.

12 Q You cited an article by Dr. Tommaselli in your
13 report of 2015. The article is from 2015.

14 Is that correct?

15 A Yes. I'm looking.

16 Q Do you have it in front of you now?

17 A Yes. The January 2015 study.

18 Q Yes.

19 A Okay.

20 Q Called Tension-Free Vaginal Tape Obturator and
21 Tension-Free Vaginal Tape-Secur for the Treatment of
22 Stress Urinary Incontinence?

23 A Yes.

24 Q So this was a five-year follow-up randomized
25 study?

1 A Yes.

2 Q And it's an RCT?

3 A Yes.

4 Q And in the Conclusion section, the authors
5 noted that, "The TVT-Secur did not show an inferior
6 subjective success rate in comparison with TVT-O five
7 years after the original procedure, even though
8 displaying a clear trend toward lower efficacy."

9 Is that right?

10 A Yes.

11 Q So there was a trend toward lower efficacy,
12 but it wasn't significantly significant?

13 A Correct.

14 MR. KOOPMANN: Those are all of the questions I
15 have for you.

16 MS. O'DELL: I have a few follow-ups,
17 Dr. Schwartz.

18 REDIRECT EXAMINATION

19 BY MS. O'DELL:

20 Q You were asked about the Abdel-fattah, Unger,
21 Welk and Jonsson Funk publications that we spoke about
22 at length this morning in regard to the TVT-O, and
23 counsel for Ethicon just asked you about them in
24 relation to TVT-Secur.

25 Each of those publications are epidemiological

1 studies that address midurethral slings as a group,
2 true?

3 A Once again, I would have to look at them, but
4 if --

5 Q From your review of them, sir, are you --
6 would you agree with me that they do not delineate among
7 patients who were implanted with either the TVT-Secur or
8 another mini-sling, true?

9 A I believe that's the case.

10 Q You were also asked about the Cochrane review
11 that was authored by Nambiar --

12 A Yes.

13 Q -- regarding single incision slings.

14 And, as I understand it, you've testified that
15 the review performed by Cochrane covered different
16 randomized controlled clinical trials than those
17 reviewed by Schimpf and others in their publication?

18 MR. KOOPMANN: Object to the form.

19 BY MS. O'DELL:

20 Q Did I understand your testimony?

21 A That they were not -- that they both did not
22 use the exact same groups.

23 Q Well, if you'll look -- and I'm sure you've
24 got Schimpf in front of you, and I know you have the
25 Cochrane review in front of you, if you'll look at

1 whichever one you have in your hand first. And I'm
2 happy to start there.

3 A Okay.

4 Q If you'll look at the Cochrane review, they
5 identified 31 RCTs with 3,290 women.

6 Do you see that on Page 3 of the exhibit under
7 Main Results?

8 A Yes.

9 Q And in the Schimpf publication on Page 2, if
10 you'll look in the literature flow chart, Figure 1,
11 you'll see that they included RCTs, 23 mini-sling RCTs,
12 correct?

13 A Yes.

14 Q And would it be fair to say -- and they were
15 published at similar time points, both in 2014, correct,
16 both the Cochrane and the Schimpf articles?

17 A Yes.

18 Q And would it be fair to say, in light of the
19 relatively small number of studies, RCTs in particular,
20 that were conducted involving the TVT-Secur, that
21 Schimpf and Cochrane would have covered the same RCTs,
22 though Cochrane included a few more, true?

23 MR. KOOPMANN: Object to form.

24 THE WITNESS: I can't say that for sure. I
25 would assume there would be overlap.

1 BY MS. O'DELL:

2 Q And substantial overlap in terms of the small
3 number of RCTs that were performed on the TVT-Secur,
4 true?

5 MR. KOOPMANN: Object to form.

6 THE WITNESS: I would assume there would be
7 overlap.

8 BY MS. O'DELL:

9 Q Okay. Based on your testimony in response to
10 Ethicon's counsel regarding the Cochrane review, are you
11 changing your testimony that a Cochrane review is a
12 reliable, credible Level 1 source of data?

13 A I am not.

14 MR. KOOPMANN: Objection.

15 THE WITNESS: I'm not changing my position.

16 BY MS. O'DELL:

17 Q And so when the Cochrane review concludes that
18 the TVT-Secur is inferior to standard midurethral slings
19 for the treatment of women with stress incontinence and
20 has already been withdrawn from the market, you have no
21 reason to disagree with their evaluation of the data,
22 correct?

23 A It is my job to question the data.

24 Q Do you have any evidence to support a
25 conclusion that the Cochrane analysis that has been

1 published regarding midurethral -- excuse me,
2 mini-slings, and specifically the comments related to
3 the TVT-Secur, are incorrect?

4 A As a result of their review, no, I do not have
5 any reason to believe that.

6 Q You rely on the Walsh study that was published
7 in 2011 or the review?

8 A Yes.

9 Q Are you aware, Dr. Schwartz, that Dr. Walsh
10 has a relationship with Ethicon?

11 A No.

12 MR. KOOPMANN: Object to the form.

13 BY MS. O'DELL:

14 Q And what's an inferiority study?

15 A It's typically to assess whether or not new
16 product is inferior to the existing product.

17 Q So it is a different structure in terms of a
18 clinical trial to a one-to-one comparison from one
19 product to another, true? In other words, the data and
20 the way that the data -- the way the data is evaluated
21 is different in an inferiority study as opposed to a
22 one-to-one comparison of efficacy and safety?

23 A I don't know the answer to that.

24 Q When you reviewed the Tommaselli study that
25 was published in the European Journal of Obstetrics in

1 2015, did you consider the fact that it was an
2 inferiority study?

3 A I read the study and do my best to assess the
4 data.

5 Q But an inferiority study is not something that
6 you are familiar with, correct?

7 MR. KOOPMANN: Object to form.

8 THE WITNESS: No. That's not what you asked
9 me before. I was asked if I understood what the
10 statistical differences were and how the data is
11 analyzed differently. That, I do not understand.
12 I haven't tried to.

13 BY MS. O'DELL:

14 Q And so when you reviewed the Tommaselli study,
15 you would not have had an appreciation of the difference
16 in the statistical analysis of an inferiority study when
17 you reviewed the data, true?

18 A I can interpret the study similarly to any
19 other study, but specifically assessing the difference
20 in the statistical analysis, I'm not familiar with.

21 MS. O'DELL: I have nothing further, Doctor.

22 MR. KOOPMANN: No.

23 (Deposition concluded at 4:45 p.m.)

24

25

CERTIFICATE OF OATH

STATE OF FLORIDA)

COUNTY OF COLLIER)

I, Elizabeth M. Brooks, Notary Public, State
of Florida, do hereby certify that, BRIAN SCHWARTZ,
M.D., personally appeared before me on the 25th day of
March, 2016, and was duly sworn.

Signed this 29th day of March, 2016.

Elizabeth M. Brooks

Notary Public

State of Florida

My Commission No. FF 014169

Expires: June 27, 2017

1 CERTIFICATE OF REPORTER

2 STATE OF FLORIDA

3 COUNTY OF COLLIER

4 I, Elizabeth M. Brooks, Registered

5 Professional Reporter, Florida Professional Reporter, do

6 hereby certify that I was authorized to and did

7 stenographically report the deposition of BRIAN

8 SCHWARTZ, M.D.; that a review of the transcript was not

9 requested, and that the foregoing transcript is a true

10 record of my stenographic notes.

11 I FURTHER CERTIFY that I am not a relative,

12 employee or attorney, or counsel of any of the parties,

13 nor am I a relative or employee of any of the parties'

14 attorney or counsel connected with the action, nor am I

15 financially interested in the action.

16 DATED this 29th day of March, 2016, at Naples,

17 Collier County, Florida.

18

19

Elizabeth M. Brooks

20 Registered Professional Reporter

Florida Professional Reporter

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